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(54) Title: IMPROVED NONWOVEN BARRIER AND METHOD OF MAKING THE SAME

(57) Abstract

A steam sterilizable nonwoven material which is subjected to charging, and more particularly electrostatic charging is provided. The nonwoven materials may include laminate nonwovens wherein one or more layers are subjected to charging. The nonwoven material(s) may also be treated with an antistatic material before or after subjecting the same to charging.

# IMPROVED NONWOVEN BARRIER AND METHOD OF MAKING THE SAME

## FIELD OF THE INVENTION

The present invention is directed to bacterial barrier fabrics. More particularly, the present invention is directed to nonwoven bacterial barrier fabrics for use as sterilization wrap, surgical draping, surgical gowns, cover garments, such as over-suits, and the like.

## BACKGROUND OF THE INVENTION

As is generally known, surgical gowns, surgical drapes, surgical face masks and sterile wrap (hereinafter collectively "surgical articles") have been designed to greatly reduce, if not prevent, the transmission through the surgical article of liquids and/or airborne contaminates. In surgical procedure environments, such liquids sources include the gown wearer's perspiration, patient liquids, such as blood and life support liquids such as plasma and saline. Examples of airborne contaminates include, but are not limited to, biological contaminates, such as bacteria, viruses and fungal spores. Such contaminates may also include particulate material such as, but not limited to, lint, mineral fines, dust, skin squames and respiratory droplets. A measure of a fabrics ability to prevent the passage of such airborne materials is sometimes expressed in terms of "filtration efficiency".

Many of these surgical articles were originally made of cotton or linen and were sterilized prior to their use in the operating room. Such surgical articles fashioned from these materials, however, permitted transmission or "strike-through" of various liquids encountered in surgical procedures. In these instances, a path was established for transmission of biological contaminates, either present in the liquid or subsequently contacting the liquid, through the surgical article. Additionally, in many instances

apparent upon further review of the following specification and claims.

SUMMARY OF THE INVENTION

In response to the above problems encountered by those of skill in the art, the present invention provides a steam sterilizable nonwoven material, such as nonwoven fabrics, formed from polymer fibers. The nonwoven materials of the present invention are formed by subjecting a portion of the nonwoven material to charging, and more particularly to electrostatic charging, and then steam sterilizing the nonwoven material. The nonwoven material may be subjected to charging followed by steam sterilization or steam sterilization followed by charging. The nonwoven material may also be treated with an antistatic material before or after subjecting the nonwoven material to charging.

These methods further include positioning another nonwoven material in a juxtaposed relationship with the first nonwoven material. Portions of the other, or second, nonwoven material may be subjected to charging before or after steam sterilization. The second nonwoven material may also be treated with an antistatic material before or after being subjected to charging.

The nonwoven materials includes a steam sterilized web formed from fibers of a polymer wherein a portion of these fibers have been subjected to charging, and particularly electrostatic charging. The steam sterilized nonwoven composition may also include an antistatic material present about portions thereof. The above nonwoven composition may further include a second web in a juxtaposed relationship to the first web. The second web may be formed from polymer fibers wherein a portion of these fibers may be subjected to charging. An antistatic treatment may also be present about portions of the second web.

The composition of the present invention further includes a nonwoven material including a first web formed from fibers of a polymer, wherein a portion of these fibers

spunbond, meltblown, spunbond material produced by Kimberly-Clark Corporation.

This spunbond, meltblown, spunbond material may be made from three separate layers which are laminated to one another. Such a method of making this laminated material is described in commonly assigned U.S. Patent NO. 4,041,203 to Brock et al which is incorporated herein in its entirety by reference. Alteratively, the spunbond, meltblown, spunbond material may be made by first forming a spunbond, meltblown laminate. The spunbond, meltblown laminate is formed by applying a layer of meltblown on to a layer of spunbond. The second layer of spunbond is then applied to the meltblown side of the previously formed spunbond, meltblown laminate. Generally, the two outer layers provide the nonwoven fabric with strength while the inner layer provides barrier properties.

The nonwoven web of the present invention may be formed from a single layer or multiple layers. In the case of multiple layers, the layers are generally positions in a juxtaposed or surface-to-surface relationship and all or a portion of the layers may be bound to adjacent layers. The nonwoven web may also be formed from a plurality of separate nonwoven webs wherein the separate nonwoven webs may be formed from single or multiple layers. In those instances where the nonwoven web includes multiple layers, the entire thickness of the nonwoven web may be subjected to charging or individual layers may be separately subjected to charging and then combined with other layers in a juxtaposed relationship to form the finished nonwoven web.

Methods of subjecting a material to charging, and particularly electrostatic charging, are well known by those skilled in the art. These methods include, for example, thermal, liquid-contact, electron beam and corona discharge methods. One particular technique of subjecting a material to electrostatic charging is the technique disclosed in U.S. Patent Application No. 07/958,958 filed

material may be applied to both the external surfaces of the nonwoven and the bulk of the nonwoven. In other instances, the antistatic material may be applied to portions of the nonwoven, such as a selected surface or surfaces thereof.

Of particular usefulness is the antistatic material known as ZELEC®, an alcohol phosphate salt product of the Du Pont Corporation. The nonwoven web may be treated with the antistatic material either before or after subjecting the web to charging. Furthermore, some or all of the material layers may be treated with the antistatic material. In those instances where only some of the material layers are treated with antistatic material, the non-treated layer or layers may be subjected to charging prior to or after combining with the antistatic treated layer or layers.

To demonstrate the attributes of the present invention, the following Examples are provided.

## Example 1

Kimberly-Clark manufactures a series of single sheet laminate nonwoven web materials made from spunbond-meltblown-spunbond (SMS) layers. These materials are available in a variety of basis weights. The nonwoven web materials used in Examples 1 and 2 were such single sheet laminate materials sold by Kimberly-Clark under the mark KIMGUARD® Heavy Duty Sterile Wrap. The basis weight of this material is 2.2 oz/sq yd. Both spunbond layers have a basis weight of 0.85 oz/sq yd and the meltblown layer has a basis weight of 0.50 oz/sq yd.

The method used to subject the samples reported in Tables 1-4 to electrostatic charging is described in the above referenced U.S. Patent Application No 07/958,958.

Referring now to Table 1, a summary of bacterial filtration efficiency (BFE) test results and standard deviation (SD) are reported for three categories

Example 2

Further analysis of the Heavy Duty KIMGUARD® Sterile Wrap (2.2 oz) were conducted to determine BFE and the charge on the samples for both pre- and post- steam sterilizing. Steam sterilization of the samples reported in Example 2 was accomplished using the steam sterilization procedure reported in Example 1. The BFE results reported in Table 2 were the product of Nelson Laboratories using the protocol described in Example 1. These BFE results represent the average of eleven non-antistatic treated samples.

Table 2

Bacterial Filtration Efficiency

(KIMGUARD® Heavy Duty Sterile Wrap)

| Description | BFE | SD% | Charge Pre | Charge Post |
|---|---|---|---|---|
| Uncharged | 90.6 | 2.3 | -- | -- |
| Charged | 98.8 | 0.31 | 800-1000 v/cm2 | -- |
| Charged /Sterilized | 94.4 | 2.0 | -- | 100-180 v/cm2 |

After charging but before steam sterilizing, a voltage of between 800 to 1,000 volts/$cm^2$, positive on one side of the material and negative on the other side of the material, was recorded. After steam sterilizing, a voltage of between 100 to 180 volts/sq cm, positive on one side and negative on the other side, was recorded. In both instances, voltage was measured using an Electrostatic Voltmeter (Trek Model 344, Trek, Inc, Median, NY) by taking ten readings on each side of the samples.

Table 3

| Sample | Product | ZELEC® | Charged | Sterilized | Avg%Red | SD | n |
|---|---|---|---|---|---|---|---|
| 1 | SPU | No | No | Yes | 71.5 | 9.1 | 25 |
| 2 | SPU | No | Yes | Yes | 87.2 | 3.1 | 25 |
| 3 | KIM | Yes | No | Yes | 69.4 | 5.7 | 15 |
| 4 | KIM | Yes | Yes | Yes | 80.8 | 9.1 | 15 |
| 5 | KIM | Yes | Yes | No | 97.2 | 1.1 | 15 |
| 6 | KIM | Yes | No | Yes | 80.1 | 9.2 | 15 |
| 7 | KIM | Yes | Yes | Yes | 88.9 | 5.7 | 15 |
| 8 | KIM | Yes | Yes | No | 94.6 | 2.7 | 15 |
| 9 | KIM | Yes | No | Yes | 73.9 | 7.6 | 15 |
| 10 | KIM | Yes | Yes | Yes | 86.2 | 4.1 | 15 |
| 11 | KIM | No | No | Yes | 66.8 | 11.9 | 15 |
| 12 | KIM | No | Yes | Yes | 94.5 | 2.8 | 15 |
| 13 | KIM | No | Yes | No | 98.2 | 0.7 | 15 |

n - Number of fabric samples.

The average percent reduction (Avg%Red) is a measurement of filtration efficiency. The Avg%Red is an expression of the reduction of number of colony forming units (CFUs) or bacteria passing through a sample compared to the number CFUs in the challenge control filter material. The Avg%Red was calculated by subtracting the number of CFUs passing through a sample from the number of CFUs passing through the challenge control filter material and dividing this number by the number of CFUs for the challenge filter material. The result was then multiplied by 100 to convert to percent.

Table 3 demonstrates that filtration properties of the steam sterilized nonwoven samples are improved by of the charging the fabric samples (Samples 2, 4, 7, 10, and 12) as compared to samples which have not been subjected to charging (Samples 1, 3, 6, 9, and 11).

TABLE 4

AVERAGE SURFACE VOLTAGE OF SAMPLES OF 2.2 OZ KIMGUARD® STERILE WRAP

| Sample # | | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|---|
| Material | Side | As Received | Charge | Sterilizer 20 min. in Dual Peel Pouch | Sterilizer 60 min. in Dual Peel Pouch | Sample #3 No Pouch Sterilizer 20 min. | Sample #4 No Pouch Sterilizer 60 min. |
| Kimguard (ZELEC®) | A | -2.8 | -125 | - 51 | -100 | 30 | - 43 |
| | B | 1.6 | - 15 | - 48 | -169 | 72 | 66 |
| Kimguard (Non-ZELEC®) | A | - 61 | 272 | 239 | -353 | -146 | -354 |
| | B | - 87 | -432 | -265 | -243 | -232 | -223 |

Notes: Sample #5 rerun of #3 without pouch
Sample #6 rerun of #4 without pouch

1. A method of manufacturing nonwoven material comprising:

charging a nonwoven web; and

steam sterilizing the nonwoven web.

2. The method of claim 1 wherein the nonwoven web is steam sterilized prior to being charged.

3. The method of claim 1 wherein the nonwoven web is charged prior to being steam sterilized.

4. The method of claim 1 wherein the charging is electrostatic charging.

5. The method of claim 1 further including the step of treating the web with an antistatic material.

6. The method of claim 1 wherein the nonwoven material comprises first and second nonwoven webs joined together in juxtaposed relationship.

7. The method of claim 6 wherein the webs are joined after the charging step.

8. The method of claim 7 wherein the first web is charged and the second web is not charged.

9. The method of claim 6 wherein the first web is treated with an antistatic material.

10. The method of claim 9 wherein the second web is treated with an antistatic material.

11. A method of manufacturing nonwoven material comprising:

charging a nonwoven web; and

treating the nonwoven web with an antistatic material.

# INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 95/02085

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 D04H13/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 D04H

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y | US-A-4 863 785 (BERMAN MARK H S ET AL) 5 September 1989 see column 2, line 16 - column 5, line 21 --- | 1,5-7, 9-11,15 |
| Y | PATENT ABSTRACTS OF JAPAN vol. 007 no. 167 (C-177) ,22 July 1958 & JP,A,58 076118 (KOUKEN KK) 9 May 1983, see abstract --- | 1,5-7, 9-11,15 |
| A | PATENT ABSTRACTS OF JAPAN vol. 011 no. 246 (C-439) ,11 August 1987 & JP,A,62 053719 (JAPAN VILENE CO LTD) 9 March 1987, see abstract --- | 1,4 |
| | -/-- | |

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance

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| Date of the actual completion of the international search | Date of mailing of the international search report |
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| 6 July 1995 | 28. 07. 95 |

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 95/02085

| Patent document cited in search report | Publication date | Patent family member(s) | | Publication date |
|---|---|---|---|---|
| US-A-4863785 | 05-09-89 | CA-A- | 1311997 | 29-12-92 |
| | | EP-A- | 0370835 | 30-05-90 |